UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re MEDTRONIC, INC. SECURITIES LITIGATION This Document Relates To: ALL ACTIONS.	Master File No. 0:13-cv-01686-JRT-FLN CLASS ACTION MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS BY DEFENDANTS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

Page

Page

STATUTES, RULES AND REGULATIONS

Pursuant to Federal Rules of Civil Procedure 26, 34 and 37, Lead Plaintiffs Employees' Retirement System of the State of Hawaii and Union Asset Management Holding AG, together with named plaintiff West Virginia Pipe Trades Health & Welfare Fund (collectively, "plaintiffs") hereby move this Court for an order compelling defendants Medtronic, Inc. ("Medtronic" or the "Company"), William A. Hawkins, Gary L. Ellis, Richard E. Kuntz, Julie Bearcroft, Richard W. Treharne, and Martin Yahiro (collectively, "defendants") to produce relevant, non-privileged documents that they have refused to produce in response to Plaintiffs' First Set of Requests for Production of Documents to All Defendants ("Requests").

I. INTRODUCTION

Despite numerous lengthy and good-faith negotiations spanning over a month, defendants have categorically refused to produce numerous relevant records responsive to Plaintiffs' Requests served on January 5, 2015. Notwithstanding plaintiffs repeated efforts to compromise and reach an agreement without resorting to court intervention, defendants:

- refuse to produce organizational charts for the relevant divisions of the Company during the Class Period that are necessary for plaintiffs' counsel to meaningfully participate in the identification of suitable custodians for e-discovery searches;
- arbitrarily limited their production to a time period that does not begin to cover the duration of the scheme alleged and upheld by the District Court, or the time period for which documents have already been gathered and produced by defendants to other parties, including the United States Senate Committee on Finance ("SFC") (General Objection 12);
- refuse to produce records concerning Medtronic's promotion, sale and marketing of INFUSE, including sales force training materials, that refer to clinical studies or trial of INFUSE or any publication regarding the safety and efficacy of INFUSE, including adverse events (Request 9);

- refuse to produce records pertaining to the Yale Study other than those relating to Medtronic's initial announcement in August 2011 that the study would be conducted (Request 16);

- refuse to produce any communications with the United States Securities and Exchange Commission ("SEC"), New York Stock Exchange ("NYSE") and the United States Department of Justice ("DOJ") or any other regulatory agency concerning Medtronic's financial results, securities or transactions involving Medtronic securities except those specifically relating to the February 22, 2011 AMPLIFY statement (Request 17);

- refuse to produce the six Individual Defendants' calendars, appointment books and similar records during the relevant period, instead artificially limiting the production to only those that explicitly refer to INFUSE or AMPLIFY from 2009-2011 (Request 19);

- refuse to produce any board or committee meeting minutes at all (Request 20);

- refuse to produce any documents or communications concerning any investigation of or litigation concerning Medtronic's promotion, marketing or sale of INFUSE or AMPLIFY, including documents previously exchanged with or made available to any foreign or domestic governmental agency regarding the same (Request 22);

- refuse to produce any records concerning any investigation of compensation of consultant physicians by Medtronic relating to any clinical study or trial of INFUSE or any publication regarding the safety and efficacy of INFUSE (including, without limitation, any adverse events) (Request 23);

- refuse to produce any sworn statements and testimony provided by Medtronic personnel in lawsuits alleging harm or death in which rhBMP-2, INFUSE or AMPLIFY were at issue except lawsuits in which harm or death is alleged to have been solely caused by medical malpractice or negligence rather than rhBMP-2, INFUSE or AMPLIFY (Request 24);

- refuse to produce any documents concerning potential violations by Medtronic personnel pertaining to rhBMP-2, INFUSE or AMPLIFY that were reported to Medtronic's *Voice Your Concern* confidential compliance hotline (Request No. 26); and

- refuse to produce documents concerning Medtronic's compliance with the Sarbanes-Oxley Act including procedures and controls for compliance with

> the Sarbanes-Oxley Act and documents concerning certifications executed by the Individual Defendants (Request 27).[1]

The information sought by the time period and each of these refused requests is not just relevant to plaintiffs' claims and/or defendants' defenses, they are central to plaintiffs' allegations and plainly falls within Rule 26(b)'s scope provision. Indeed, many of these Requests call for documents that Medtronic has already produced, perhaps more than once, in separate litigation, strongly suggesting that defendants refusal to produce them here stems not from any concerns about burden, but rather from an attempt to simply keep relevant documents out of plaintiffs' reach.

Through the meet-and-confer process, plaintiffs have offered to substantially narrow most, if not all, of the records sought by these improperly refused requests to reduce any burden on defendants in producing such relevant records. To date, despite the fact that plaintiffs' Requests were served on January 5, 2015, the only records defendants have produced are a portion of the records previously produced to the SFC and a handful of organizational charts – some of which were illegible when produced – that do not encompass the relevant period, predate the Class Period, and do not even cover the period for which defendants agreed to produce records.

Defendants' refusal to produce records relevant to plaintiffs' claims – never mind their dilatory approach to producing other categories of undisputedly responsive records – is not permissible under the federal rules. Consequently, defendants should be ordered to

[1] "Class Period" refers to the time period from September 8, 2010 to August 3, 2011, inclusive.

comply with plaintiffs' Requests 9, 16-17, 19-20, 22-24, 26-27 and promptly produce all non-privileged responsive records for the requested time period.

II. FACTUAL AND PROCEDURAL BACKGROUND

The Court has upheld the allegations in the Complaint which claim that, unbeknownst to investors, throughout the Class Period – and in fact dating back to at least 2000 – defendants engaged in a fraudulent scheme and course of conduct in violation of §10(b) of the Securities Exchange Act of 1934 by withholding evidence obtained from clinical studies and editing medical articles to downplay or conceal the risks associated with rhBMP-2, thereby increasing confidence in the product and driving sales. ¶¶87, 124, 125-129.[2] As part of their scheme, and as was later revealed with the publication of the October 2012 SFC Report ("Senate Staff Report"), defendants surreptitiously drafted and edited medical journal articles that purportedly had been written by physician consultants and excised true facts from clinical trials regarding the efficacy and side effects of INFUSE. *See* ¶¶17, 35, 87, 105, 107, 125, 127, 129. Defendants did so with the knowledge that patients treated with INFUSE experienced adverse events at statistically significant rates compared to non-INFUSE patients. ¶¶36, 37, 87, 99. Defendants also edited clinical trial reports to grossly overstate the disadvantages of iliac crest bone graft ("ICBG") – the "standard" of care prior to INFUSE – to make INFUSE appear to be a more desirable alternative. ¶¶87, 107. Indeed, the rhBMP-2 studies were systematically designed to bias the results in favor of INFUSE with respect to both adverse events and efficacy. ¶¶87, 108. In furtherance of the scheme,

[2] All citations to "¶" or "¶¶" are to the Consolidated Class Action Complaint for Violations to the Federal Securities Laws (Dkt. No. 28) ("Complaint"), filed on November 4, 2013. Unless otherwise noted, all emphasis is added and all citations and footnotes are omitted.

Medtronic paid the purported authors of the INFUSE articles – physicians who consulted for the Company – between $560,000 to a staggering $24 million dollars. ¶¶87, 106. All told, between 1996 and 2010, Medtronic's paid consultants reaped $210 million dollars. ¶125.

On the evening of May 25, 2011, *The Spine Journal* published a study highlighting the risk of retrograde ejaculation ("RE") (which causes male sterility) in patients treated with INFUSE. ¶¶26, 89. The article, based upon a retrospective analysis of INFUSE patients over a 3-year period, revealed that there was a twelve-fold increase in RE among INFUSE users. *Id*. In response, Medtronic claimed that the data did not support a statistically significant link between INFUSE and male sterility. ¶¶28, 96, 99. As would be disclosed in October 2012, Medtronic had known such a link existed since 2001. ¶¶36-37.

Approximately one month later, on June 28, 2011, *The Spine Journal* devoted an entire issue to INFUSE in which the authors further detailed the risks and side effects associated with INFUSE, revealing that the incidence of adverse events among INFUSE users was many times greater than what had been disclosed in the original publications, ranging as high as 50%. ¶¶30, 103-104. The early Medtronic-funded INFUSE studies published between 2002 and 2009 uniformly reported no adverse events associated with rhBMP-2. ¶105. These articles also revealed that complications with ICBG had been greatly overstated in the early INFUSE studies. ¶107. Perhaps most significantly, the article titled "Folly of FDA-Approval Studies for Bone Morphogenetic Protein," detailed how early INFUSE trials, funded by Medtronic and conducted by its highly-paid consultants, were systematically designed to elicit results favorable to INFUSE. ¶108. The June 28, 2011 issue of *The Spine Journal* likewise revealed that the apparent conflicts of interest by those

conducting and reporting on INFUSE trials were massive: the median range of financial incentives was $12 to $16 million per study – far exceeding the nominal amount in the original study journals' disclosures. ¶¶30, 106. Significant as it was, the June 28, 2011 issue of *The Spine Journal* did not reveal Medtronic's covert participation in drafting the early INFUSE medical literature.

In the wake of *The Spine Journal* articles, Medtronic announced on August 3, 2011, that it would publicly release INFUSE data for Yale researchers to conduct a review. Thereafter, Yale commissioned two separate, independent, systematic reviews of individualized patient data from all Medtronic-sponsored clinical studies of INFUSE and AMPLIFY conducted by Oregon Health & Science University ("OHSU") and University of York ("York") to answer the question: compared with ICBG, does rhBMP-2 safely improve outcomes of spinal fusion surgery? The results of the reviews appeared in the June 2013 issue of *Annals of Internal Medicine*, and confirmed the assertions made in *The Spine Journal* two years earlier:

> [A]fter systematic evaluation and synthesis of all available evidence, both systematic reviews published here independently conclude that rhBMP-2, compared with iliac crest bone grafting, does not improve pain or function and increases adverse events, possibly including cancer.

¶¶120-124.

On October 25, 2012, after gathering and reviewing internal documents provided to it by Medtronic, the SFC issued the Senate Staff Report concerning the Company's influence over INFUSE clinical trials. ¶125. The Senate Staff Report revealed for the first time

Medtronic's material (and previously undisclosed) role in shaping the medical literature purporting to establish INFUSE's safety and efficacy, including that:

- Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants and covertly participated in the peer review process. ¶¶125, 129.
- Medtronic officials inserted language into studies that promoted INFUSE as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique. ¶125.
- Internal company documents, including a 2001 Powerpoint presentation, indicated that defendants actually knew of a statistically significant occurrence of retrograde ejaculation among INFUSE users. ¶128.
- A Medtronic employee recommended against publishing a complete list of adverse events possibly associated with INFUSE in a 2005 *Journal of Bone & Joint Surgery* article. ¶¶125, 127.

In support of these conclusions, the Senate Staff Report referenced, and made publicly available, several internal company documents, including Powerpoint presentations and emails with the Company's highly-paid consultants, none of which were previously available to the public. ¶¶125-129.

In addition to these scheme claims in violation of SEC Rule 10b-5(a) and (c), the Complaint alleges defendants Medtronic and Hawkins violated SEC Rule 10b-5(b) by making materially false and misleading statements concerning AMPLIFY, a second-generation, higher-dosage BMP, for which Medtronic was attempting to secure United States Food and Drug Administration ("FDA") approval. ¶¶22, 24. In its quarterly financial report for the third quarter of fiscal 2011, filed on March 9, 2011, Medtronic disclosed that sometime before January 28, 2011, it received the news that the FDA would not approve

AMPLIFY for market. ¶79. However, on February 22, 2011, Hawkins falsely represented to investors that the Company was unsure at that time of AMPLIFY's approval status. ¶73.

Pursuant to the Private Securities Litigation Reform Act of 1995, all discovery was stayed during the pendency of defendants' motions to dismiss. On September 29, 2014, this Court largely upheld the Complaint against defendants' motion to dismiss. Dkt. No. 76.[3] Thereafter, on January 5, 2015, plaintiffs served defendants with their first set of requests for production of documents. *See* Ex. 1 attached to the Declaration of Christopher M. Wood in Support of Memorandum of Law in Support of Plaintiffs' Motion to Compel Production of Documents by Defendants ("Wood Decl."), filed concurrently herewith. Defendants responded to the requests on February 9, 2015. *See* Wood Decl., Ex. 2. Between February 16, 2015 and March 10, 2015, the parties engaged in extensive and thorough meet-and-confer efforts regarding several objections and requests, including General Objection 12 and Requests 9, 13, 16-17, 19, 20, 22-24, 26-27, which remain in dispute. *Id.*, Exs. 2-3.

III. ARGUMENT

As the Supreme Court has recognized, "[m]odern instruments of discovery serve a useful purpose" to "make a trial less a game of blindman's buff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent." *United States v. Procter & Gamble Co*., 356 U.S. 677, 682 (1958) (citing *Hickman v. Taylor*, 329 U.S. 495, 507 (1947) ("[m]utual knowledge of all the relevant facts gathered by both parties is essential to

[3] Claims against former defendants Thomas A. Zdeblick, M.D., Scott D. Boden, M.D., and J. Kenneth Burkus, M.D., all of whom consulted for Medtronic at relevant times, were dismissed. The Court upheld plaintiffs' scheme liability allegations, as well as Hawkins' February 22, 2011 statement regarding the status of Medtronic's market approval application for AMPLIFY.

proper litigation")). Indeed, the Eighth Circuit has affirmed that "[b]road discovery is an important tool for the litigant." *WWP, Inc. v. Wounded Warriors Family Support, Inc*., 628 F.3d 1032, 1039 (8th Cir. 2011).

In fact, the federal rules expressly provide that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). Relevance under Rule 26 "has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978). Moreover, discovery is not limited to the specific issues raised in the parties' pleadings because "discovery itself is designed to help define and clarify the issues." *Id.* Thus, "[i]nformation is generally discoverable 'unless it is clear that the information sought has ***no bearing*** upon the subject matter of the action.'" *Shukh v. Seagate Tech., LLC*, 295 F.R.D. 228, 237 (D. Minn. 2013).

The party seeking discovery must make a "threshold showing" that the information requested falls within the '"wide scope of discovery under Rule 26."' *Honeywell Int'l, Inc. v. Furuno Elec. Co*., No. 09-cv-3601 (MJD/TNL), 2013 U.S. Dist. LEXIS 76929, at *3 (D. Minn. May 30, 2013). Once that showing is made, the "'party resisting discovery must show specifically how each . . . request for production is not relevant or how each question is overly broad, burdensome or oppressive.'" *Nye v. Hartford Accident & Indem. Co*., No. Civ. 12-5028-JLV, 2013 U.S. Dist. LEXIS 85299, at *21 (D.S.D. June 18, 2013). To satisfy this heavy burden, the resisting party must specifically detail the reasons why each request is improper; "'[b]oilerplate objections are unacceptable.'" *Id.*

Defendants have not come close to demonstrating a justification for withholding the documents at issue.

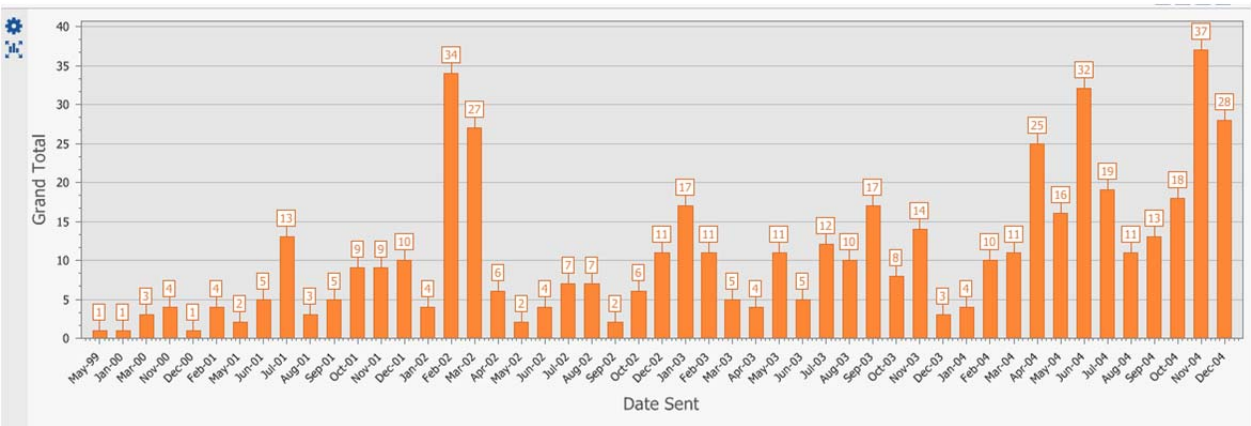
A. Defendants' Time Period Objection Lacks Merit

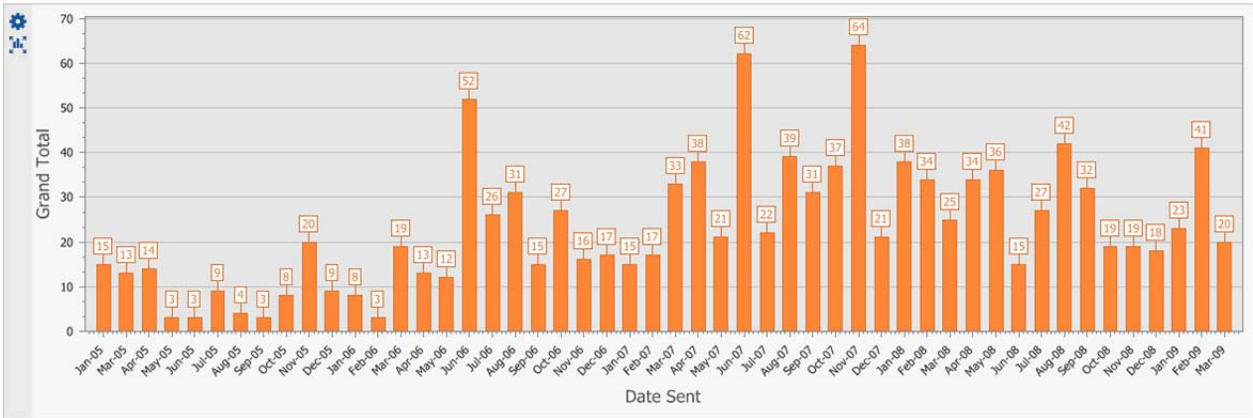
Plaintiffs' original time period for the requests was January 1, 2000 through the date of production. Wood Decl., Ex. 1 at 11. Defendants objected, stating that January 1, 2009 through December 31, 2011 would apply to their production ("Defendants' Time Period"). *Id.*, Ex. 5 at 1. During the meet-and-confer process, plaintiffs consented to Defendants' Time Period for Requests 14-17 and 27 and shortened the time period for all other requests to January 1, 2000 through December 31, 2013 ("Plaintiffs' Time Period"). *Id.*, Exs. 3 at 2, 6 at 1. Defendants continue to object to Plaintiffs' Time Period for remaining requests. *Id.*, Ex. 5.

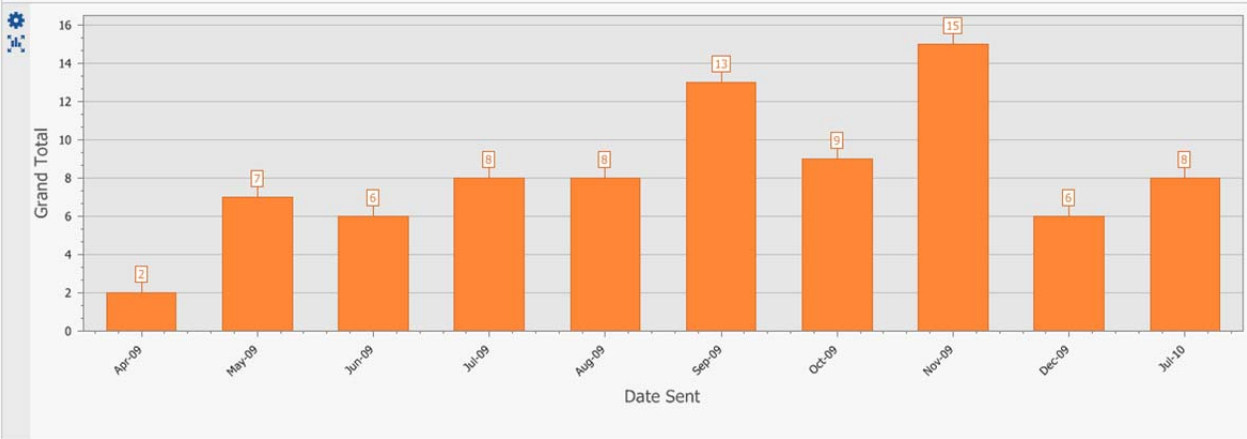
Contrary to defendants' position, Plaintiffs' Time Period is appropriate considering that defendants' scheme is alleged to have begun prior to the FDA's approval of INFUSE in 2002. *See* ¶¶9-21; *see also* Dkt. No. 76 at 3-4, 20-21, 53, 57. Based on the materials revealed by the 2012 Senate Staff Report, plaintiffs believe many of the acts in furtherance of the scheme occurred between 2000-2011. Indeed, the 13 original Medtronic-sponsored rhBMP-2 publications identified in *The Spine Journal* span 2000 through 2009. ¶87(b) and Ex. A thereto. And, the SFC found that Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010. Dkt. No. 76 at 12. The SFC also determined that "Medtronic employees, including employees working for its marketing department, collaborated with physician authors, many of whom had significant financial relationships with Medtronic" to draft

studies dated between 2002 and 2009. Complaint, Ex. C at 6. The SFC further noted that policies regarding interactions between Medtronic and physician authors were implemented between 2006 and 2011. *Id.* at 7-9.

Indeed, Medtronic has already produced e-mails dated during a similar time period to the SFC which was investigating similar claims. The following charts set forth the volume of Medtronic emails per month which were included in the production to the SFC:







Defendants have yet to articulate a credible reason why documents produced in this action should not pre-date 2009 as most of the documents produced to the SFC do.

Accordingly, because Plaintiffs' Time Period is closely correlated with the duration of the alleged scheme, it is "reasonably calculated to lead to the discovery of admissible evidence." *In re Control Data Corp. Sec. Litig.*, No. 3-85-1341, 1987 U.S. Dist. LEXIS 16829, at *7-*8 (D. Minn. Dec. 10, 1987) (concluding that the class period – the approximate period defendants here advocate – "does not determine the period of relevancy for discovery purposes"), *aff'd*, No. 3-85 CIV 1341, 1988 U.S. Dist. LEXIS 18603 (D. Minn. Feb. 22, 1988). Indeed, particularly in securities cases like this, courts have long recognized that a defendant's "attempt to confine discovery to a narrow period" immediately pre- and post-dating the class period "is artificial, arbitrary and designed to avoid the production of relevant documents." *In re Seagate Tech. II Sec. Litig.*, No. C-89-2493(A)-VRW, 1993 U.S. Dist. LEXIS 18065, at *2-3 (N.D. Cal. June 10, 1993). The reason is simple: "[a] class period is delimited in order to identify the individuals who claim membership in the class, not to identify the conduct that injured them" and "this is why it is called the '***Class*** Period,'

not the 'Liability Period.'" *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 643 n.27 (S.D.N.Y. 2007) (emphasis in original).

Courts recognize that "[a]ny information that sheds light on whether class period statements were false or materially misleading is relevant," and that both pre- and post-class period information is relevant in determining what defendants knew or should have known during the class period. *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001); *Lapin v. Goldman Sachs Grp., Inc.*, 506 F. Supp. 2d 221, 236-37 (S.D.N.Y. 2006) (finding, on motion to dismiss, that pre-class-period statements were '"relevant in determining whether defendants had a duty to make a corrective disclosure during the Class Period"' and that post-Class Period statements may be relied upon "'"to confirm what a defendant should have known during the Class Period"'"). Moreover, a "scheme to defraud under the securities laws may include efforts to conceal the fraud or avoid detection" which is why "where intent is a critical issue, there is no hard and fast rule fixing a relevant discovery time period" and "there is no general rule which would limit class action discovery solely to the class period." *Grossman v. First Pa. Corp.*, No. 89-9234, 1992 U.S. Dist. LEXIS 2266, at *4-*5 (E.D. Pa. Feb. 24, 1992). Consequently, based on the nature of the alleged scheme here which dates back to at least 2000, Plaintiffs' Time Period is appropriate for Requests 1-13, 18-26 and 28-29.

Accordingly, plaintiffs respectfully request that the Court order defendants to comply with Plaintiffs' Time Period for Requests 1-13, 18-26 and 28-29.

B. Defendants' Boilerplate Objections to Requests 9, 16-17, 19-20, 22-24 and 26-27 Lack Merit and Do Not Excuse Their Failure to Comply with the Requests

"The party opposing discovery has the burden to show that its objections are valid by providing explanation or factual support." *Hohn v. BSNF Ry. Co*., No. 8:05CV552, 2007 U.S. Dist. LEXIS 34546, at *5 (D. Neb. May 10, 2007) *aff'd*, No. 8:05CV552, 2007 U.S. Dist. LEXIS 65751 (D. Neb. Sept. 4, 2007). "'Bare assertions that discovery requested is overly broad, unduly burdensome, oppressive or irrelevant are ordinarily insufficient . . . to bar production.'" *Id.* at *5-*6 (alteration in original); *Nye*, 2013 U.S. Dist. LEXIS 85299, at *12 (same). Defendants' objections here are entirely conclusory and boilerplate and thus fail to justify their refusal to produce responsive records. *See* Wood Decl., Ex. 2.

Moreover, defendants' general contention that the evidence plaintiffs seek is irrelevant because defendants believe the claims lack merit and may be time barred do not excuse their refusal to comply with the requests. Indeed, it is axiomatic that no party possesses the "unilateral ability to dictate the scope of discovery based on their own view of the parties' respective theories of the case." *Sentis Grp., Inc. v. Shell Oil Co.*, 763 F.3d 919, 925 (8th Cir. 2014) (quoting Fed. R. Civ. P. 26(b)(1) ("'Parties may obtain discovery regarding any nonprivileged matter that is relevant to ***any party's claim or defense*** . . . .'") (emphasis and alteration in original)).

Nor does defendants' conclusory assertion of burden withstand scrutiny because "generally '[a]ll discovery requests are a burden on the party who must respond thereto. Unless the task of producing . . . is unusual, undue or extraordinary, the general rule requires the entity . . . producing the documents to bear that burden.'" *Jenkins v. Pech*, No.

8:14CV41, 2015 U.S. Dist. LEXIS 20837, at *8 (D. Neb. Feb. 19, 2015) (some alterations in original); *see also Sinco, Inc. v. B. & O. Mfg.*, No. 03-5277 (JRT/FLN), 2005 U.S. Dist. LEXIS 12086, at *5-*6 (D. Minn. May 23, 2005) (finding defendant's statement that "it will take approximately 300 hours" to respond to plaintiff's requests did "not adequately demonstrate that responding will be unduly burdensome"). Defendants' belief in their affirmative defenses also does not obviate the need to comply with plaintiffs' Requests. *See David v. Alphin*, No. 3:07cv11, 2010 U.S. Dist. LEXIS 144275, at *18-*19 (W.D.N.C. Mar. 30, 2010) ("Discovery under Rule 26 is not . . . limited to materials upon which liability can or cannot be founded"); *Beesley v. Int'l Paper Co.*, No. 06-703-DRH, 2008 U.S. Dist. LEXIS 5093, at *3-*5 (S.D. Ill. Jan. 24, 2008) ("[D]iscovery as to events outside the statute of limitations is appropriate where the information is 'otherwise relevant to the issues in the case.' . . . [The acts] which occurred during the limitations period may well have resulted from seeds sown outside the period.").

Ultimately, the federal rules advisory committee has "caution[ed] courts to keep in mind that decisions as to relevance at the discovery stage are being made 'well in advance of trial'" and "a 'flexible treatment of relevance [at the discovery stage] is required.'" *Nye*, 2013 U.S. Dist. LEXIS 85299, at *10 (alteration in original). Defendants have failed to carry their burden to justify not producing the relevant records plaintiffs seek and should be compelled to promptly comply with the Requests.

1. Request 9: Documents Concerning Medtronic's Promotion, Sale and Marketing of INFUSE

Request 9 seeks "documents concerning Medtronic's promotion, sales and marketing of INFUSE, for any indication including, but not limited to, sales force training materials." Wood Decl., Ex. 1 at 12. Defendants' objection to this Request is relevancy. *Id.*, Ex. 2 at 7. In response to defendants' objection, plaintiffs offered to narrow the Request to seek "documents concerning Medtronic's promotion, sales and marketing of INFUSE including, but not limited to, sales force training materials, that refer to any clinical study or trial of INFUSE or any publication regarding the safety and efficacy of INFUSE including, without limitation, any adverse events." *Id.*, Ex. 3 at 3. Even with the narrowing of the Request, defendants refuse to produce any records responsive to this Request.

Defendants' objection is not well-founded because the Complaint alleges a scheme whereby Medtronic set a corporate goal before FDA approval in 2002 to have INFUSE replace ICBG as the standard of care in spinal fusion. *See* ¶9; Dkt. No. 76 at 45. In order for INFUSE to become the standard of care and drive sales, its safety and efficacy needed to be supported by clinical evidence demonstrating that patients who used INFUSE had better results and less adverse side effects compared to patients undergoing more traditional bone graft procedures. *Id*. The Complaint also alleges that, while early INFUSE clinical studies designed and sponsored by Medtronic revealed significant safety risks that would threaten Medtronic's corporate goal of replacing ICBG as the standard of care, the Company embarked on a scheme with physician consultants to conceal the significant safety risks from the public and physician community. ¶¶15-17; Dkt. No. 76 at 45-46.

As a result of the alleged scheme and course of conduct, defendants caused the publication of the original industry-sponsored clinical research studies to report almost zero adverse events or side effects connected with INFUSE. ¶18. And, due to industry-sponsored literature that reported no adverse events attributed to INFUSE, spine surgeons began using INFUSE for an array of procedures, both FDA-approved and "off-label," leading to a dramatic increase in the number of spine fusions augmented by rhBMP-2. ¶¶8, 19. Sales and revenue growth was explosive; the number of spine fusions augmented by rhBMP-2 soared from 0.7% in 2002 to 25% in 2006. *Id.*; Dkt. No. 76 at 46, 57.

Based on these and other allegations in the Complaint pertaining to the alleged scheme that the Court upheld, the relevance of the information sought is "apparent on the face of the request." *SEC v. Kovzan*, No. 11-2017-JNL, 2013 U.S. Dist. LEXIS 23754, at *3 (D. Kan. Feb. 21, 2013). Defendants have failed to offer any explanation as to why this information falls outside the scope of relevancy and should be compelled to promptly produce records responsive to Request 9.

2. Request 16: Documents Concerning the Yale Study

Request 16 seeks "documents and communications concerning the Yale Study." Wood Decl., Ex. 1 at 14. Defendants object to this Request as overbroad, burdensome and seeking irrelevant information, and have only agreed to produce the published results of the Yale Study and such non-privileged records as may exist around the time of the announcement that the study would be taking place, in August 2011. *Id.*, Ex. 2 at 10, Ex. 6 at 3.

While the published results of the Yale Study are certainly encompassed by this Request, the Company's involvement, participation, and internal reaction to the Yale Study are also highly relevant to plaintiffs' claims. The Complaint alleges that the Yale Study confirmed rhBMP-2 was no more effective than ICBG, and in fact caused more adverse events. ¶¶121-124. The Yale Study also confirms that the studies at issue were indeed manipulated and misleading throughout the Class Period. *Id.* Clearly documents related to an independent study that confirms the Complaint's allegations are relevant to plaintiffs' claims, and considering there is only a single Yale Study at issue for a narrow time period, defendants' unsubstantiated claims of over-breadth and burden ring hollow.

Again, the relevance of the information sought is "apparent on the face of the request." *Kovzan*, 2013 U.S. Dist. LEXIS 23754, at *3. Defendants fail to offer any explanation as to why this request is over-broad, or that the information sought is actually burdensome or falls outside the scope of relevancy. *See Rawat v. Navistar Int'l Corp*., No. 08 C 4305, 2011 U.S. Dist. LEXIS 98432, at *24 (N.D. Ill. Sept. 1, 2011) ("Navistar must do more than make broad assertions that producing the documents would be difficult, and the fact that an exceptionally large number of documents is involved does not speak for itself on this issue"), *aff'd*, No. 08-CV-0438, U.S. Dist. LEXIS 139759 (N.D. Ill. Dec. 5, 2011).

The information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 16.

3. Request 17: Communications to Governmental and Regulatory Agencies

Request 17 seeks:

> [D]ocuments concerning any communications between you and the SEC, New York Stock Exchange, U.S. Department of Justice or any other regulatory agency concerning Medtronic's financial results, securities or transactions involving Medtronic securities, including all documents filed with the SEC, received from the SEC or concerning any SEC filing made or to be made in connection with or on behalf of Medtronic, including drafts of proposed filings and drafts of documents actually filed with the SEC.

Wood Decl., Ex. 1 at 14. Defendants' objections to this request are relevance and that it is not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 10. Defendants have only agreed to produce records relating to the February 22, 2011 alleged misstatement regarding AMPLIFY. *Id.*

While the February 22, 2011 AMPLIFY statement is the only remaining false statement, the Complaint alleges an overarching scheme in violation of the federal securities laws that had the intended effect of materially impacting Medtronic's financial statements and artificially inflating its stock price. Dkt. No. 76 at 19-21. Moreover, defendants' unilateral limitation of the information sought by this request is unjustifiable because the Request seeks information not just from the SEC, but from the NYSE, DOJ, or any other regulatory agency concerning Medtronic's financial results, securities or transactions involving Medtronic securities. And, plaintiffs have already agreed to limit this production to Defendants' Time Period (2009-2011).

The Supreme Court has previously explained that discovery is not limited to the specific issues raised in the parties' pleadings "because discovery itself is designed to help define and clarify the issues." *Oppenheimer*, 437 U.S. at 351. Defendants' conclusory objections to this Request do not relieve them of the burden to respond. The information

sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 17.

4. Request 19: Calendars and Records of Business Activities

Request 19 seeks "calendars, diaries, daybooks, appointment books, telephone logs, or similar documents reflecting the Medtronic business activities of each Individual Defendant." Wood Decl., Ex. 1 at 14. Defendants' objections to this Request include over-breadth, burden, not reasonably calculated to lead to the discovery of admissible evidence, and harassment. *Id.*, Ex. 2 at 11. Defendants have only agreed to produce records for the Class Period if they expressly refer or relate to INFUSE or AMPLIFY. *Id.*

Calendars and similar records used in day-to-day business management are plainly relevant and discoverable. *United States v. MacKey*, 647 F.2d 898, 901 (9th Cir. 1981). Further, where, like here, there is evidence that defendants avoided using email to discuss sensitive topics, calendars and phone logs are important evidence of a defendants' involvement in an alleged scheme. *E.g.*, Ex. 7 at MDT000094488 (Medtronic marketing manager asking another Medtronic employee to "call me to discuss this matter via phone," when asked about inquiries into INFUSE-related deaths); Ex. 8 at MDT000028135 (Bearcroft responding to Burkus that she will call an inquiring doctor to discuss his "disappoint[ment] in the lack of reference to statistical" data in study about INFUSE); Ex. 9 at MDT000016908 (Wyeth Pharmaceuticals employee asking Medtronic employees to "call me to discuss" an article in *The Wall Street Journal* article about adverse events related to off-label use of INFUSE "as our executive management is inquiring as to [Medtronic's] response").

The information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 19.

5. Request 20: Board Materials

Request 20 seeks "documents prepared for, distributed to, created in connection with or used in any Board of Directors meeting (whether formal or informal and including committee meetings of the Board) including, but not limited to, board packages, financial closing packages, meeting minutes, exhibits, agendas, memoranda and resolutions, whether adopted or discussed." Wood Decl., Ex. 1 at 14-15. Defendants object to this Request on the grounds that it is overly broad as to the word "meeting," unduly burdensome, seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 12. In response to defendants' objection, plaintiffs offered to narrow this Request as follows:

January 1, 2000 through September 27, 2010 and August 4, 2011 through December 31, 2013	All final board or committee meeting agendas and full board packets during the time period that reference INFUSE or AMPLIFY.
September 28, 2010 through August 3, 2011	All final board or committee meeting agendas and full board packets.

Id., Ex. 3 at 4. Despite this narrowing, defendants continue to stand by their objections.

Board materials are not categorically immune from discovery. *See, e.g.*, *SEC v. Banc de Binary*, No. 2:13-cv-993-RCJ-VCF, 2014 U.S. Dist. LEXIS 155259, at *10 (D. Nev. Oct. 30, 2014) (granting SEC's motion to compel production of "all board minutes"). Here, Medtronic's board minutes are particularly relevant as to the element of scienter, or defendants' knowledge of the scheme. Defendant Hawkins was Chairman of the Board until

he retired from the Company in June 2011. ¶47. Medtronic's Board was also accused of breaching its fiduciary duty in connection with allegations similar to those at issue in this action, and has already conducted an investigation into those claims, where presumably many of the documents at issue in this Request will have already been retrieved and reviewed. Ex. 10.

Defendants have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly comply with Request 20.

6. Request 22: INFUSE Investigations and Litigation

Request 22 seeks "documents and communications concerning any investigation of or litigation concerning Medtronic's promotion, marketing or sale of INFUSE or AMPLIFY for any indication, whether or not such indication was approved by the FDA including, but not limited to, all documents exchanged by you and any foreign or domestic government entity regarding such promotion, marketing or sale." Wood Decl., Ex. 1 at 14. Defendants object to this Request on the basis that it is overly broad, seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 12. In response to defendants' objection, plaintiffs offered to narrow this request as follows:

> "All documents and communications concerning any investigation of or litigation concerning Medtronic's promotion, marketing or sale of INFUSE or AMPLIFY including, but not limited to, all documents exchanged or made available by you and any foreign or domestic government entity regarding such promotion, marketing or sale, that refer to any clinical study or trial of

> INFUSE or any publication regarding the safety and efficacy of INFUSE including, without limitation, any adverse events."

Id., Ex. 4 at 5. Despite this narrowing, defendants continue to stand by their objections.

Related litigation and materials previously produced in connection therewith are routinely required to be produced. *See Rawat*, 2011 U.S. Dist. LEXIS 98432, at *23-*25 (granting plaintiffs' motion to compel defendants' production of documents in related litigation and previously produced to governmental agency). As the court in *Rawat* articulated when considering a similar request and objection:

> The company has already produced these once, and it provides no information on what it would have to do to comply with Plaintiffs' request. Navistar does not state, for example, whether a copy of its earlier production already exists, what records of its production were retained, or other specific information concerning the burden of responding to Plaintiffs. Presumably, Navistar will not be required to re-collect the documents as if they were being assembled for the first time. Nor need it sift through them to identify items it believes to be relevant to this case; Plaintiffs only ask for the documents Navistar did, in fact, produce in *Ustian*, and the company can turn those documents over to Plaintiffs without a relevance review. Accordingly, Navistar has not shown how the burdens of producing these documents outweigh Plaintiffs' need to view them.

Id. at *24-*25. Similarly, the defendants in *Rawat* objected to reproducing documents previously provided to a governmental agency because of the sheer volume of records which numbered in the millions of pages. *Id.* at *32. The court was unpersuaded that the volume alone constituted burden because defendants failed to articulate "what expense would be involved in giving Plaintiffs what Navistar has already given to the SEC." *Id.* at *33. "In the absence of specific arguments from Navistar on this issue, the Court cannot conclude that the company has carried its burden of proof to demonstrate that producing materials that

have already been collected, organized, and turned over to the SEC would be unduly burdensome." *Id.* at *38.

Here, Medtronic has been engaged in myriad litigation related to INFUSE over the past seven-plus years including separate class action litigation, derivative litigation, personal injury actions, litigation with insurance companies, as well as investigations by the SFC and the DOJ. Because these actions and investigations at least relate to the claims at issue here, there is no justification for withholding documents previously produced in those actions, which would involve minimal if any cost.

As in *Rawat*, defendants here have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 22.

7. Request 23: Investigations into the Compensation of Physician Consultants

Request 23 seeks "documents and communications concerning any investigation of compensation of consultant physicians by Medtronic including, but not limited to, all documents exchanged by you and any government entity regarding such compensation." Wood Decl., Ex. 1 at 15. Defendants object to this Request on the basis that it is overly broad, seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 13. In response to defendants' objection, plaintiffs offered to narrow this request as follows:

> "All documents and communications concerning any investigation of compensation of consultant physicians by Medtronic relating to any clinical

> study or trial of INFUSE or any publication regarding the safety and efficacy of INFUSE (including, without limitation, any adverse events), including, but not limited to, all documents exchanged or made available by you and any government entity regarding such compensation."

Id., Ex. 3 at 5. Despite this narrowing, defendants continue to stand by their objections.

The compensation of consultant physicians by Medtronic relating to clinical studies and publications regarding INFUSE's safety and efficacy go to the heart of the scheme allegations in this case. *See supra* §II. As such, their relevance is "apparent on the face of the request." *Kovzan*, 2013 U.S. Dist. LEXIS 23754, at *3. Defendants have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 23.

8. Request 24: INFUSE Lawsuits

Request 24 seeks "documents concerning any lawsuits against Medtronic in which it is alleged that rhBMP-2 caused any person any physical harm or death, including all testimony or sworn statements given by any Medtronic personnel concerning rhBMP-2, INFUSE or AMPLIFY." Wood Decl., Ex. 1 at 15. Defendants object to this Request because it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 13. In response to defendants' objection, plaintiffs offered to narrow this request as follows: "all sworn statements and testimony provided by Medtronic personnel in lawsuits alleging harm or death from rhBMP-2, INFUSE or AMPLIFY." *Id.*, Ex. 3 at 5. Despite this narrowing, defendants continue to stand by their objections.

Testimony and sworn statements provided by Medtronic personnel in lawsuits alleging harm or death from rhBMP-2, INFUSE or AMPLIFY are undoubtedly relevant and discoverable. In *United States Bank N.A. v. PHL Variable Ins. Corp.*, No. 12-CV-877 (JRT/TNL), 2013 U.S. Dist. LEXIS 183018 (D. Minn. Jan. 18, 2013), Judge Tunheim ordered the production of transcripts of testimony by the defendants' current or former employees from other cases involving similar facts because the "[d]epositions and associated exhibits could contain or lead to admissible evidence concerning what [defendant] knew at the time [of the underlying conduct]." *Id.* at *13.[4]

Defendants have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 24.

[4] *See also Burks v. Abbott Labs.*, No. 08-3414(JRT/JSM), 2011 U.S. Dist. LEXIS 125457, at *8 (D. Minn. Oct. 31, 2011) (Tunheim, J.) (upholding Magistrate Judge's order compelling the production of deposition transcripts from prior litigation because the "deposition transcripts are relevant to the remaining issues in the case because they may 'contain evidence that reflects Abbott's knowledge'" regarding the alleged contamination of the product as well as "how it formulated its package labeling and warnings"'); *Biben v. Card*, 119 F.R.D. 421, 428 (W.D. Mo. 1987) (finding transcripts of defendants' testimony before the SEC were discoverable and not protected by the work product doctrine because "such transcripts contain statements concerning the action or its subject matter previously made by a party to the action" which "statements are obtainable by another party without a showing that the party seeking discovery has substantial need of the materials in the preparation of the party's case and that the party is unable without undue hardship to obtain the substantial equivalent of the materials by other means").

9. Request 26: Violations of Codes of Conduct and Compliance Complaints

Request 26 seeks "documents concerning Medtronic's corporate code(s) of ethical conduct, code(s) of business conduct, and Corporate Integrity Agreements, and all documents concerning actual, reported or potential violations by any officer, employee, agent or director including, but not limited to, reports concerning Medtronic's *Voice Your Concern* confidential compliance hotline." Wood Decl., Ex. 1 at 16. Defendants object to this Request because it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 14. In response to defendants' objection, plaintiffs offered to narrow this Request as follows: "all documents concerning actual, reported or potential violations by any officer, employee, agent or director including, but not limited to, reports concerning Medtronic's *Voice Your Concern* confidential compliance hotline, pertaining to rhBMP-2, INFUSE or AMPLIFY during the time period January 1, 2000 through December 31, 2013." *Id.*, Ex. 3 at 6. Despite this narrowing, defendants continue to stand by their objections and have stated their intent to limit their production to Medtronic's corporate code(s) of ethical conduct and code(s) of business conduct. *Id.*, Ex. 2 at 14.

While Medtronic's ethical and business conduct codes are encompassed by this request, those two categories of records are but a tiny subset of the records requested. Defendants' response indicated no records would be produced concerning actual, reported or potential violations by any officer, employee, agent or director including, but not limited to, reports concerning Medtronic's *Voice Your Concern* confidential compliance hotline. Any

such reports are plainly relevant to the scheme alleged whereby Medtronic is alleged to have clandestinely edited journal articles to remove and downplay any concerns about the safety and efficacy of INFUSE while handsomely paying for the services of several physician consultants to sponsor studies and author journal articles attesting to INFUSE's safety and efficacy.

Defendants have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 26.

10. Request 27: Sarbanes-Oxley Records

Request 27 seeks "[d]ocuments concerning Medtronic's compliance with the Sarbanes-Oxley Act including, but not limited to policies, procedures and controls for compliance with the Sarbanes-Oxley Act and documents concerning certifications executed by any Individual Defendant." Wood Decl., Ex. 1 at 16. Defendants object to this Request because it seeks irrelevant information and information not reasonably calculated to lead to the discovery of admissible evidence. *Id.*, Ex. 2 at 14.

The relevance of information related to Sarbanes-Oxley certificates and compliance in an action alleging securities violations is "apparent on the face of the request." *Kovzan*, 2013 U.S. Dist. LEXIS 23754, at *3. Defendants have offered nothing other than conclusory and boilerplate objections to the information sought by this Request. Nonetheless, the information sought by this Request is well within the scope of Rule 26(b)(1) and defendants should be compelled to promptly produce records responsive to Request 27.

IV. CONCLUSION

As the party resisting discovery, defendants bear the burden of articulating specific reasons justifying their refusal to comply with a Request. Here, despite ample opportunities, defendants have merely offered boilerplate assertions of relevance, over-breadth and burden. Accordingly, plaintiffs respectfully request that the Court order defendants to comply with plaintiffs' Requests by producing records for Plaintiffs' Time Period and in response to Requests 9, 16-17, 19-20, 22-24 and 26-27.

DATED: April 27, 2015

Respectfully submitted,

ROBBINS GELLER RUDMAN
& DOWD LLP
CHRISTOPHER M. WOOD

s/ Christopher M. Wood
CHRISTOPHER M. WOOD

414 Union Street, Suite 900
Nashville, TN 37219
Telephone: 615/244-2203
615/252-3798 (fax)
cwood@rgrdlaw.com

ROBBINS GELLER RUDMAN
& DOWD LLP
SHAWN A. WILLIAMS
EKATERINI M. POLYCHRONOPOULOS
Post Montgomery Center
One Montgomery Street, Suite 1800
San Francisco, CA 94104
Telephone: 415/288-4545
415/288-4534 (fax)
shawnw@rgrdlaw.com
katerinap@rgrdlaw.com

ROBBINS GELLER RUDMAN
& DOWD LLP
ARTHUR C. LEAHY
DANIELLE S. MYERS
SUSANNAH R. CONN
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)
artl@rgrdlaw.com
dmyers@rgrdlaw.com
sconn@rgrdlaw.com

MOTLEY RICE LLC
JAMES M. HUGHES
DAVID P. ABEL
CHRISTOPHER F. MORIARTY
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Telephone: 843/216-9000
843/216-9450 (fax)
jhughes@motleyrice.com
dabel@motleyrice.com
cmoriarty@motleyrice.com

Lead Counsel for Plaintiffs

ZIMMERMAN REED, PLLP
CAROLYN G. ANDERSON, MN 275712
ANNE T. REGAN, MN 333852
BRIAN C. GUDMUNDSON, MN 336695
1100 IDS Center, 80 South 8th Street
Minneapolis, MN 55402
Telephone: 612/341-0400
612/341-0844 (fax)
Carolyn.Anderson@zimmreed.com
Anne.Regan@zimmreed.com
Brian.Gudmundson@zimmreed.com

Liaison Counsel

PRICE OKAMOTO HIMENO
LUM
WARREN PRICE, III
ROBERT A. MARKS
728 Ocean View Center
707 Richards Street
Honolulu, HI 96813
Telephone: 808/538-1113
808/533-0549 (fax)

Additional Counsel for Plaintiffs